REMARKS

This Preliminary Amendment is responsive to the Office Action dated October 31, 2002. Entry of the amendments and remarks submitted herein and reconsideration of the claimed subject matter is respectfully requested.

At the outset, Table 1 on page 16 of the specification was amended above to delete most of the amendments submitted on August 12, 2002, as requested by the Examiner (Office Action, page 4). However, the amendment to the name change of LFA-1 was not rescinded, nor was the amendment correcting the characterization of PNAd-1. Both of these amendments were made to correct typographical errors, which is clearly the case for LFA-1. As for PNAd-1, the fact that the original entry was a typographical error is evidenced by the attached abstract (1991, J. Biol. Chem.) and article (1993, Nature) (ref. #10 cited in the specification on page 78), each by Berg *et al.*, which show that PNAd and MAdCAM-1 both contain the same L-selectin binding domain to which MECA-79 binds. As explained in the Nature article by Berg *et al.*, this domain supports adhesion of L-selectin-transfected lymphoid cells under shear (see the abstract). Given that PNAd-1 contains the same MECA-79 (L-selectin) binding domain, it can be inferred that PNAd-1 also functions under shear conditions, as was known to the inventor at the time the application was filed.

In addition, an abstract on a separate sheet (page 93) has been provided with this Amendment, as requested in the Office Action. No prohibited new matter has been added by way of these amendments.

Turning now to the Office Action, the Examiner has renumbered claims 113 and 114 as claims 12 and 113, apparently because there is no record of a claim 112 previously

submitted in the file. Accordingly, Applicants submit along with this Amendment a copy of the Supplemental Amendment filed on July 30, 2001, which presented claim 112 for examination. This amendment was submitted directly to the Examiner's attention via facsimile in response to a request from the Examiner that a Supplemental Amendment be submitted to reset his time clock for acting on the application. Applicants respectfully request entry of claim 112 as submitted on July 30, 2001, and renumbering of claims 113 and 114 as appropriate.

Claim 112 appears to correspond to the elected invention. Accordingly, Applicants confirm, as stated in the Office Action dated October 31, 2002, that claims 55-59, 62-64, 67, 68, 72, 76, 80, 83, 86, 87, 89, 90, 98-106, 109 remain pending and are under examination, along with renumbered claims 112-114. Claims 60, 61, 65, 66, 69-71, 73-75, 77-79, 81, 82, 84, 85, 88, 91-97, 107, 108 and 110-111 remain withdrawn as being directed to a non-elected invention.

Page 4 of the Office Action indicates that the abstract filed with the original specification as page 93 could not be located in the file, but that providing the abstract on a separate sheet at this time would suffice. Accordingly, Applicants have attached hereto a separate page 93 containing an abstract reading on the claimed invention.

The amendment filed August 12, 2002, was objected to for allegedly introducing new matter into Table 1 at page 16. Without necessarily agreeing with the objection, Applicants have amended Table 1 above to rescind most of the amendments filed August 12, 2002. As explained above, the amendment to the name change of LFA-1 was not rescinded, as this corrected an obvious typographical error. In addition, the amendment correcting the characterization of PNAd-1 was also submitted to correct a typographical

error. The fact that the original entry as to the characterization of PNAd-1 was a typographical error is evidenced by the attached abstract (1991, J. Biol. Chem.) and article (1993, Nature) (ref. #10 cited in the specification on page 78), each by Berg *et al.*, which show that PNAd and MAdCAM-1 both contain the same L-selectin binding domain to which MECA-79 binds. As explained in the Nature article by Berg *et al.*, this domain supports adhesion of L-selectin-transfected lymphoid cells under shear (see the abstract). Given that PNAd-1 contains the same MECA-79 (L-selectin) binding domain, it can be inferred that PNAd-1 also functions under shear conditions, as was known to the inventor at the time the application was filed. In view of the amendments and remarks submitted above, reconsideration and withdrawal of the objection is respectfully requested.

Claims 55-59, 62-64, 67, 68, 72, 76, 80, 83, 86, 87, 89, 90, 98-106, 109 and newly added claims 112 and 113 (which should be renumbered as claims 113 and 114, respectively) were rejected under 35 U.S.C. §102(e) as being allegedly anticipated by Cutler *et al.* (US 5,578,309) (hereinafter the '309 patent). According to the Office Action, the '309 patent is an invention "by another" as set forth in MPEP 2136.04 despite Applicants' priority claim, and therefore the rejection is proper. Applicants respectfully traverse the rejection.

The '309 patent does not disclose the genus covered by the pending claims. The species that the reference does disclose, *i.e.*, compositions comprising phosphomannoprotein adhesins from *C. albicans*, does not make the claimed genera obvious, because there is no disclosure of the general concept, *i.e.*, that isolated pathogen adhesin molecules that bind to a host cell or extracellular matrix under shear conditions

are particularly useful in a vaccine, or a diagnostic assay kit or composition, or a therapeutic composition.

The species disclosed in the '309 patent is the invention of Yongmoon Han and Jim Cutler. The species disclosed in the reference is cited in claims 76 and 83, which refer to *Candida* and *Candida albicans*, respectively. Accordingly, Han and Cutler are the inventors of the common material and therefore the priority claim to the '309 patent is proper. However, the more general concept covered by the claims, *i.e.*, that pathogen adhesin molecules in general that bind to a host cell or extracellular matrix under shear conditions are broadly applicable to vaccines, assay kits and therapeutic compositions, was invented by other inventors in addition to Han and Cutler, and was not obvious in view of the '309 patent at the time the application was filed.

Furthermore, the Examiner has grouped all the claims into the rejection without pointing out where the reference teaches each of the claimed limitations. For instance, the '309 patent does not teach a pathogen adhesin molecule that functionally mimics a ligand for a host cell molecule, such as a selectin or integrin as recited in claims 58, 59, 106, 113 and 114. The reference makes no mention of an ICAM-1 host cell adhesion molecule as recited in claims 62, 67 and 109, or a protein, glycoprotein or mannose-containing host cell adhesion molecule as recited in claims 62-64. The reference does not concern host cells from the nasopharynx and alveoli as recited in claim 80, nor does it mention peptide mimetics as recited in claims 90 and 98. If the rejection is maintained, Applicants respectfully request that the Examiner point out with particularity where the '309 patent teaches each of the claimed limitations.

Thus, while the '309 patent discloses a species within the claimed genus, this species does not make the claimed genus obvious. Furthermore, the species was invented by Han and Cutler, who are inventors of the currently claimed subject matter. There are many other limitations in the current claims that are not disclosed in the '309 patent and have a different inventorship than the species disclosed in the '309 patent. Since Han and Cutler are inventors of the common material, the priority claim to the '309 patent is proper. In view of these remarks, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

Applicants note that in the process of performing the inventorship analysis, it was determined that Clifford Bond and Gordon McFeters were erroneously included as inventors. A Petition to Correct the Inventorship under 37 CFR 1.48(a), along with consent forms signed by both assignees and statements in support of the petition signed by Clifford Bond and Gordon McFeters, respectively, are submitted with this Preliminary Amendment. In addition, it was discovered that James Burritt and Don Burgess are no longer inventors of any pending claims, even though they were properly included as inventors in the application as filed. A Petition to Correct the Inventorship under 37 CFR 1.48(b) is also attached, as is a new declaration signed by the appropriate inventors.

This reply is fully responsive to the Office Action dated October 31, 2002. Therefore, a Notice of Allowance is next in order and is respectfully requested. Seeing as the species being examined is allowable, Applicants respectfully request that the Examiner move on to examine another species.

Except for issue fees payable under 37 CFR §1.18, the commissioner is hereby authorized by this paper to charge any additional fees during the pendency of this application including fees due under 37 CFR §1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 CFR §1.136(a)(3).

If the Examiner has any further questions relating to this Reply or to the application in general, he is respectfully requested to contact the undersigned by telephone so that allowance of the present application may be expedited

Respectfully submitted,

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Dated: April 30, 2003

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APPENDIX

The following amendments were entered above:

The table at page 16, line 14, was amended as follows:

Table 1

Adhesion Molecules Examined Under Shear

Adhesion Molecules Expressed on Optimal Function Conditions

	Leukocyte	Endothelium	Shear	Static
E-selectin	-	+	+	-
P-selectin	-	+	+	± [+/-]
L-selectin	+	-	+	-
MAdCAM-1	-	+	+	+
PNAd-1	+	+	+	-
VCAM-1	+	+	-/+ [+]	+
ICAM-1	+	+	± [+/-]	+
Mac-1	+	-	-	+
LFA-1	+	-	-	± [+/-]
VLA4	+	-	-/+ [+]	+
beta-1	+	+	-/+	+
LPAM	+	-	+	+

ABSTRACT OF THE DISCLOSURE

Therapeutic peptides, vaccines and diagnostic agents are disclosed that may be used for the treatment and diagnosis of pathogenic infections. In particular, a vaccine comprising an isolated pathogen adhesin molecule or immunogenic fragment thereof is provided, wherein the pathogen adhesin molecule or fragment thereof binds to an adhesion molecule on a host cell or extracellular matrix under shear conditions.

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